Initial Approval: January 8, 2020

CRITERIA FOR PRIOR AUTHORIZATION

Narcolepsy Agents

BILLING CODE TYPE For drug coverage and provider type information, see the KMAP Reference Codes webpage.

MANUAL GUIDELINES: Prior authorization will be required for all current and future dose forms available. All medication-specific criteria, including drug-specific indication, age, and dose for each agent is defined in table 1 below.

Pitolisant (Wakix®)
Sodium Oxybate (Xyrem®)
Solriamfetol (Sunosi®)

GENERAL CRITERIA FOR INITIAL PRIOR AUTHORIZATION: (must meet all of the following)

- Must be approved for the indication, age, and not exceed dosing limits listed in Table 1.
- For all agents listed, the preferred PDL drug, if applicable, which treats the PA indication, is required unless the patient meets the non-preferred PDL PA criteria.
- Diagnosis of narcolepsy has been confirmed in accordance with International Classification of Sleep Disorders – Third Edition (ICSD-3) listed in table 2.[1]
- If the requested drug is for the treatment of excessive daytime sleepiness (EDS) (must meet both of the following):
  - Patient must have failed a 6-week trial of modafinil and/or armodafinil.[2]
  - Prescriber must provide the patient's baseline Epworth Sleepiness Scale (ESS) score.[3]
- If the requested drug is for the treatment of cataplexy, prescriber must provide patient's baseline frequency of cataplexy episodes per month.

LENGTH OF APPROVAL (INITIAL): 3 months

CRITERIA FOR RENEWAL PRIOR AUTHORIZATION: (must meet all of the following)

- If the requested drug is for the treatment of EDS, patient has an improvement (reduction) in ESS score.
- If the requested drug is for the treatment of cataplexy, patient has a decrease or maintained a decrease in the number or severity of cataplexy episodes per month.
- Must not exceed dosing limits listed in Table 1.

LENGTH OF APPROVAL (RENEWAL): 12 months

FOR DRUGS THAT HAVE A CURRENT PA REQUIREMENT, BUT NOT FOR THE NEWLY APPROVED INDICATIONS, FOR OTHER FDA-APPROVED INDICATIONS, AND FOR CHANGES TO AGE REQUIREMENTS NOT LISTED WITHIN THE PA CRITERIA:

- **THE PA REQUEST WILL BE REVIEWED BASED UPON THE FOLLOWING PACKAGE INSERT INFORMATION: INDICATION, AGE, DOSE, AND ANY PRE-REQUISITE TREATMENT REQUIREMENTS FOR THAT INDICATION.**

LENGTH OF APPROVAL (INITIAL AND RENEWAL): 12 months

Table 1. FDA-approved age and dosing limits for Narcolepsy Agents.[4-6]

Agents	Indication(s)	Age	Dosing Limits
Analeptics			
Pitolisant (Wakix®)	Narcolepsy with associated excessive daytime sleepiness	≥ 18 years	35.6 mg orally daily CYP2D6 poor metabolizers: 17.8 mg orally daily
Solriamfetol (Sunosi®)	Narcolepsy with associated excessive daytime sleepiness	≥ 18 years	150 mg orally daily
Psychotherapeutic Agents			
Sodium Oxybate (Xyrem®)	Narcolepsy with associated excessive daytime sleepiness Narcolepsy with cataplexy (type 1 narcolepsy)	≥ 7 years	Adults: 9 grams per night Pediatrics*: ≥ 45 kg: 4.5 grams per dose and 9 grams per night 30 to < 45 kg: 3.75 grams per dose and 7.5 grams per night 20 to < 30 kg 3 grams per dose and 6 grams per night

*There is no specific dosing provided in the manufacturer's labeling (insufficient information) for those weighing under 20 kg. Consider lower initial dosage, lower maximum weekly dosage increases, and lower total maximum nightly dosage.

Table 2. ICSD-3 diagnostic criteria for narcolepsy type 1 and 2.[1]

Type 1 narcolepsy	Type 2 narcolepsy
Alternate Names: Hypocretin deficiency syndrome, narcolepsy-cataplexy, narcolepsy with cataplexy. Diagnostic Criteria: A and B must be met. A. The patient has daily periods of irrepressible need to sleep or daytime lapses into sleep occurring for at least three months. B. The presence of one or both of the following: 1. Cataplexy (as defined under Essential Features) and a mean sleep latency of ≤ 8 minutes and two or more sleep onset REM periods (SOREMPs) on an MSLT performed according to standard techniques. A SOREMP (within 15 minutes of sleep onset) on the preceding nocturnal polysomnogram may replace one of the SOREMPs on the MSLT. 2. CSF hypocretin-1 concentration, measured by immunoreactivity, is either ≤ 110 pg/mL or <1/3 of mean values obtained in normal subjects with the same standardized assay.	Alternate Names: Narcolepsy without cataplexy. Diagnostic Criteria: A-E must be met. A. The patient has daily periods of irrepressible need to sleep or daytime lapses into sleep occurring for at least three months. B. A mean sleep latency of ≤ 8 minutes and two or more sleep onset REM periods (SOREMPs) are found on a MSLT performed according to standard techniques. A SOREMP (within 15 minutes of sleep onset) on the preceding nocturnal polysomnogram may replace one of the SOREMPs on the MSLT. C. Cataplexy is absent. D. Either CSF hypocretin-1 concentration has not been measured or CSF hypocretin-1 concentration measured by immunoreactivity is either > 110 pg/mL or > 1/3 of mean values obtained in normal subjects with the same standardized assay. E. The hypersomnolence and/or MSLT findings are not better explained by other causes such as insufficient sleep, obstructive sleep apnea, delayed sleep phase disorder, or the effect of medication or substances or their withdrawal.

References

1. Quality measures for the care of patients with narcolepsy. J Clin Sleep Med 2015;11(3):33-355. Available at http://jcsm.aasm.org/ViewAbstract.aspx?pid=29931. Accessed 12/30/19.
2. Practice parameters for the treatment of narcolepsy and other hypersomnias of central origin. *Sleep* 30.12 (2007): 1705-1711. Available at https://academic.oup.com/sleep/article/30/12/1705/3741350. Accessed on 12/9/19.
3. Johns, Murray W. A new method for measuring daytime sleepiness: the Epworth sleepiness scale. *Sleep* 14.6 (1991):540-545. Available at https://academic.oup.com/sleep/article/14/6/540/2742871. Accessed 12/30/19.
4. Wakix (pitolisant) [prescribing information]. Plymouth Meeting, PA: Harmony Biosciences LLC; August 2019.
5. Xyrem (sodium oxybate) [prescribing information]. Palo Alto, CA: Jazz Pharmaceuticals; October 2018.
6. Sunosi (solriamfetol) [prescribing information]. Palo Alto, CA: Jazz Pharmaceuticals Inc; June 2019.

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